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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/417,175	10/11/1999	NANCY J. HARPER	PC10139AMAG	7073

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GREGG C BENSON
PFIZER INC
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER
OH, TAYLOR V

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 08/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/417,175	HARPER ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-10,12 and 14-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 7-10, 12, and 14-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Final Rejection

The Status of Claims

Claims 1, 7-10, 12, and 14-20 have been rejected.

Claim Rejections - 35 USC 103

1. Applicants' argument filed 6/2/2003/2002 have been fully considered but are persuasive.

Rejection of Claims 1, 7-10, 12, and 14-20 under 35 U.S.C. 103 (a) as being unpatentable over Doogan et al (U.S. 4,962,128) in view of Howard et al (U.S. 5,597,826) and Johnson (EP 768083).

The rejection of Claims 1, 7-10, 12, and 14-20 under 35 U.S.C. 103(a) as being unpatentable over Doogan et al (U.S. 4,962,128) in view of Howard et al (U.S. 5,597,826) and Johnson (EP0768083) is maintained for the reasons of the record in paper no. 16.

Claim Rejections - 35 USC § 112

Claims 15 and 17 are rejected under 35 U.S.C. 112, first paragraph. Claims 15 and 17 are directed to the method for preventing and treating diseases, such as cancers. The specification falls short because data essential for preventing cancers is not described in the specification. In the absence of specific malignant tumors or otherwise, data showing inhibition of the multiplication of cancer cells, such a broad assertion is not believable in view of the

contemporary knowledge of the art. 34 USPQ 2d, 1436 (Fed Cir. 1995) . See also, MPEP 2107.01, 2107.02. 2107.03, 2164.01©, 2164.04, 2164.07.

Moreover, the claim sets forth the treatment of cancer generally. However, there are more than 3000 cancers. Applicants have not identified a specific compound capable of treating "cancers" broadly. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. Even the most broadly effective anti-tumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally, evidence that the level of skill in this art is low relative to the difficulty of such a task. See also, In re Joller, 206 USPQ 885(CCPA 1980).

Response to Argument

Applicants argue the following issues:

1. the Doogan et al has failed to teach the preparation of non-aqueous liquid concentrate compositions of sertraline and has directed to the use of water as a primary diluent in the liquid preparation ;

2. there is no teaching in the Howard et al or the Johson that would lead the skillful artisan to obtain an essentially non-aqueous , filterable liquid concentration of sertraline with 18 mg/ml to 78 mg/ml ;

3. there is no teaching in the Johnson that would lead the skillful artisan to obtain an essentially non-aqueous , filterable liquid concentration of sertraline with 18 mg/ml to 78 mg/ml ;

4. applicants' non-aqueous liquid concentrate for oral administration having unique amount and combination of excipients have resulted in unexpected properties ;

5. the Examiner has not supplied the motivation to combine the references to achieve the non-conventional, non-aqueous liquid concentrate having the unique amounts and combination of excipients;

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the first argument, the Examiner has noted applicants' argument. However, the Doogan et al does teach the composition contains setraline or its pharmaceutically acceptable salt, flavoring agents, and diluents ,such as ethanol, glycerin and various like combinations thereof; also, the secondary Howard et al reference to supplement the primary reference does disclose that liquid preparations containing sertraline may be prepared by conventional means with pharmaceutically acceptable additives such as non-aqueous vehicles (see col. 22 ,lines 47-55). Furthermore, it is well-known in the art that many liquid preparations of conventional means with pharmaceutically acceptable additives are available depending upon

the customer's choice. Therefore, if the skillful artisan in the art had desired to develop the product containing non-aqueous liquid concentrate compositions of sertraline, it would have been obvious for the skillful artisan in the art to have motivated to incorporate Howard et al 's non-aqueous vehicles into the Doogan et al method because, for oral administration, Howard et al does indicate that non-aqueous vehicles can be incorporated in the liquid preparations containing sertraline .

Second, with respect to the second argument, the Examiner has noted applicants' argument. However, the Doogan et al does teach that it is administered in dosages ranging from 50-500 mg /day (see col. 2 , lines 20-21); oral pharmaceutical formulations can be flavored by means of various agents ; the composition contains sertraline with concentration levels ranging from 0.5 % to 90 % by weight of the total compositions (see col. 2 ,lines 45-46) or its pharmaceutically acceptable salt, flavoring agents, and diluents such as ethanol, propylene glycol, and glycerin (see from col. 2 line 65 to col. 3, line 2). Also, the Howard et al reference does teach the dose of 0.3mg to 10mg per kg of body weight per day of the sertraline (see col. 23, lines 33-34). Furthermore, the filterable liquid concentration of the sertraline is naturally obtained as a result of the process, but is unrelated to the novelty of the invention; this does not add any patentable weight over the prior art reference. Therefore, if the skillful artisan had desired to develop the product containing non-aqueous liquid concentrate compositions of sertraline, it would have been obvious for the skillful artisan in the art to have motivated to incorporate Howard et al 's non-aqueous vehicles into the Doogan et al method, thereby ascertaining the claimed dose by routine experimentation. This is because, for oral

administration, Howard et al does indicate that non-aqueous vehicles can be incorporated in the liquid preparations containing sertraline .

Third, concerning the third argument, the Examiner has noted applicants' argument. However, the Johnson reference has been withdrawn from the rejection . Therefore, applicants' argument are irrelevant.

Fourth, concerning the fourth argument, the Examiner has noted applicants' argument. However, applicants' argument of unexpected results can not take the place of evidence in the record. In re DeBlauwe, 736 F. 2d 699, 705, 222 U.S.P.Q. 191, 196 (Fed. Cir. 1984).

Fifth, regarding the fifth argument, the Examiner has noted applicants' argument. However, there is a motivation to combine the references. Doogan et al does disclose the pharmaceutical composition containing sertraline hydrochloride (see col. 1, line 68) with a dose from 25 mg to 200 mg for treating anxiety-related disorders (see col. 2, lines 20-23); in addition, oral pharmaceutical formulations can be flavored by means of various agents ; the composition contains sertraline or its pharmaceutically acceptable salt, flavoring agents, and diluents such as ethanol, propylene glycol, and glycerin (see from col. 2 line 65 to col. 3, line 2). If elixirs are desired for oral administration , the sertraline may be combined with various flavoring agents 6(see from col. 2 lines 63-67).

Howard et al discloses expressly the pharmaceutical composition containing sertraline hydrochloride (see col. 20, line 31) with a dose from 0.1 mg to 200 mg (see col. 24, lines 7-8), suspending agents, non-aqueous vehicles such as ethyl alcohol, and preservatives (see col. 22,

lines 51-56); in addition, oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58). Also, the reference indicates that pharmacologically acceptable anions include methanesulfonate (see col. 20, lines 60-61). Both prior art references are definitively dealt with the pharmaceutical composition containing sertraline hydrochloride with an overlapping dose; both do describe that the pharmaceutical composition containing sertraline hydrochloride may be combined with various pharmaceutically acceptable inert carrier in the form of syrups and solutions. Therefore, if the skillful artisan had desired to develop the product containing non-aqueous liquid concentrate compositions containing sertraline and methanesulfonate as pharmacologically acceptable anions, it would have been obvious for the skillful artisan in the art to have motivated to use Howard et al 's methanesulfonate into the Doogan et al pharmaceutical composition containing sertraline hydrochloride because, for oral administration, both do indicate that non-aqueous vehicles can be incorporated in the liquid preparations containing sertraline . Therefore, there is the motivation to combine the references rejection references to achieve the non-aqueous liquid concentrate having the unique amounts and combination of excipients by routine experimentations.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703) 308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

8/24/03

Alan L Rotman

ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600